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IN THE

Supreme Court of the United States

October Term, 1964

No. [redacted] 224

DETROIT VITAL FOODS, INC.,

Petitioner.

AGAINST

UNITED STATES OF AMERICA,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

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No. .....

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DETROIT VITAL FOODS, INC.,

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AGAINST

UNITED STATES OF AMERICA,

Respondent.

—o—

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

Petitioner prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Sixth Circuit entered in the above-entitled case on March 31st, 1964.

Citations to Opinions Below

The opinion of the District Court is printed in Appendix A, *infra*, page 16, and is officially reported at 192 F. Supp. 51 (1961).

The opinion of the Court of Appeals is printed in Appendix A, *infra*, page 20, and is officially reported at 330 F. 2d 78 (1964).

Jurisdiction

The judgment of the Court of Appeals was entered on March 31, 1964 and its mandate stayed pending the filing of this petition. The jurisdiction of this Court is invoked under 28 U. S. C. 1254(1).

Questions Presented

1. Whether a product, manufactured and sold within a state, is being "held for sale after shipment in interstate commerce" within the meaning of 21 U. S. C. 334, by reason of the fact that it is composed of ingredients which moved in interstate commerce.

2. Whether the Federal Food, Drug and Cosmetic Act, 21 U. S. C. 334, may be constitutionally construed to permit the assertion of Federal jurisdiction over an alleged misbranding of a product while in the hands of a retailer which has been manufactured and created within the same state from interstate ingredients.

Statutes Involved

The statutory provision involved is Section 304 of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. 334. There is also involved Article I, Section 8, Clause 3, and the Tenth Amendment to the Constitution of the United States. The applicable statute and constitutional provisions are printed in Appendix B, *infra*, page 30.

Statement

This is a petition for a writ of certiorari to review an order and judgment of the United States Court of Appeals for the Sixth Circuit entered on March 31, 1964.

which affirmed so much of the decree of the United States District Court for the Eastern District of Michigan, Southern Division, as adjudges that the product known as "Michigan Brand Korleen" was misbranded while held for sale after shipment in interstate commerce within the meaning of Section 304 of the Federal Food, Drug and Cosmetic Act.

The question in issue was whether the District Court has jurisdiction under the Federal Food, Drug and Cosmetic Act for the alleged misbranding of a product which never moved in interstate commerce. The product was manufactured and distributed locally. The ingredients used to manufacture the product originated from out of state and were fully consumed in the manufacturing process. The ingredients are not alleged to have been misbranded herein.

Facts

This is a civil action *in rem* brought under the purported authority of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. 301 *et seq.* to condemn 39 cases of the product known as "Michigan Brand Korleen", and other products not involved herein.

The libel of information alleges that the product was misbranded while held for sale after shipment in interstate commerce under 21 U. S. C. 334. Petitioner, a retail store, intervened as claimant and entered an answer denying the misbranding and the District Court's jurisdiction over the subject matter of the action.

The libel further alleges that the petitioner misbranded the product by utilizing literature which allegedly contained false and misleading statements, in violation of 21 U. S. C. 352(a).

The sole reference in the libel to the movement of the product in interstate commerce is that the product was delivered to petitioner "via local truck," after having been manufactured and packed by Freshman Vitamin Corp., the manufacturer, in Oak Park, Michigan from raw ingredients received by the manufacturer in interstate commerce on various occasions during 1959 and 1960. The libel does not charge that the ingredients were misbranded at any time either when introduced into, while in, or while held for sale after shipment in interstate commerce, and indeed, it is not even alleged that the ingredients were held for sale.

It is apparently the premise of the libel that seizure and condemnation under the Federal Food, Drug and Cosmetic Act is proper with respect to a product in the hands of a retailer, even though the product never moved in interstate commerce, and was manufactured and sold intrastate, merely because the ingredients used by the manufacturer, had at one time moved in interstate commerce.

The undisputed facts concerning the manufacture of the product are that the product was manufactured by Freshman Vitamin Corp., a separate and wholly independent entity having no connection or relationship with the petitioner retail store except that of manufacturer and customer. It is further undisputed that the product was manufactured from ingredients, consisting of choline, inositol, methionine, cysteine, niacinamide and excipients, which are in common use in the industry, were not made to the specifications of either the manufacturer or petitioner and which, after being used in the manufacturing process, were fully consumed and no longer identifiable as individual ingredients.

As distinguished from other cases which have arisen under the Federal Food, Drug and Cosmetic Act, there is here involved an attempt to invoke jurisdiction over a *new* product in the hands of a retail store merely because the ingredients used in the manufacture of the product had at one time moved in interstate commerce.

Petitioner moved the District Court for summary judgment on the ground that the District Court lacked constitutional authority and statutory jurisdiction over the product.

The District Court denied petitioner's motion, but failed to meet either the constitutional question posed or the issue of statutory construction as to whether the product was "being held for sale after shipment in interstate commerce" within the meaning of the Act.

The Court of Appeals affirmed and held that the misbranding of a product made from ingredients that had been properly labeled in the course of interstate commerce, came within the prohibitory provisions of the Act. The Court upheld the constitutionality of this interpretation on the authority of *United States* v. *Sullivan*, 332 U. S. 689 (1948).

With respect to the allegations of the libel that the product was "being held for sale after shipment in interstate commerce" within the meaning of Section 304 of the Act, the Court of Appeals held that the manufactured product was not different from the ingredients from which it was manufactured. This finding was made without any support in the record and is premised upon the contention that advertising references by the retailer to the ingredients, destroyed the product's physical existence as a newly manufactured product.

Reasons for Granting the Writ

Petitioner respectfully submits that certiorari should be granted in that a basic constitutional question is presented involving the Federal Government's jurisdiction under the Commerce clause. Certiorari is also necessary to correct the Court of Appeals' erroneous interpretation of this Court's decision in *United States* v. *Sullivan*, *supra*. Furthermore, the instant case is one of public importance in that it presents a recurring question of statutory construction involving the jurisdiction of the Federal Government under the Federal Food, Drug and Cosmetic Act.

1. Petitioner respectfully submits that the Court of Appeals' decision transgresses constitutional authority in that it has applied the Federal Food, Drug and Cosmetic Act to a factual situation so extreme as to obliterate all distinctions between interstate and intrastate commerce. In the instant case, the product was manufactured and sold within the same state. The ingredients used in the manufacture of the product came from outside the state and were fully consumed in the manufacturing process in the creation of the new product here in issue. The Court of Appeals' decision has created a new rule that interstate commerce never ceases—*i.e.*, that there is no point at which interstate commerce terminates and local trade commences. The decision by the Court of Appeals results in an unconstitutional extension of Federal powers in areas which historically have not only been left to state regulation, but with respect to which adequate redress is available in the Food and Drug laws enacted by almost every state in the United States.

2. Petitioner respectfully submits that the Court of Appeals has erroneously interpreted this Court's decision in *United States v. Sullivan, supra*, and has over-looked other prior decisions of this Court construing the Federal Food, Drug and Cosmetic Act and the constitutional limitations thereunder.

The *Sullivan* case, *supra*, involved a construction of 21 U. S. C. 331(k) and the question of whether intervening sales of a drug could destroy Federal jurisdiction.* In that case, a drug had moved in interstate commerce and was being held by a retail pharmacist who had removed the drug from its properly labeled package and obliterated its label. In sustaining Federal authority under 21 U. S. C. 331(k), this Court held that it was immaterial how many intervening sales had occurred after the interstate shipment, so long as the product had at one time moved in interstate commerce since jurisdiction under 331(k) attached to prohibit the mutilation or obliteration of the package label. It was in this connection that this Court had occasion to observe that the words "while such article is held for sale (whether or not the first sale) after shipment in interstate commerce" were intended to extend the Act's coverage to every product which had gone through interstate commerce from the moment of introduction into interstate commerce to the moment of delivery to the ultimate consumer. But surely, this statement may not be deemed sufficient to support Federal jurisdiction over a newly manufactured product which itself had never moved in interstate commerce.

It thus appears that the Court of Appeals has misconstrued this Court's holding in the *Sullivan* case, *supra*.

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* The language in Section 331(k) "while held for sale (whether or not the first sale) after shipment in interstate commerce" became part of 21 U. S. C. 331(a) by the enactment of the Miller Amendment in 1948; 62 Stat. 582.

Neither the *Sullivan* case, *supra*, nor this Court's prior decisions on the subject * can be construed to authorize the seizure and condemnation of a product in the hands of a retailer, and allegedly misbranded by him, where the product has never moved in interstate commerce and whose only connection with interstate commerce is that the ingredients, consumed in its manufacture, at one time moved in interstate commerce.

The fact that the retailer may have misbranded the product by advertising references to the ingredients of the product cannot bridge the gap of supplying constitutional authority over the article. The retailer cannot, by his words, confer jurisdiction if it never existed.

United States v. *40 Cases . . . Pinocchio Brand*, 289 F. 2d 343 (C. A. 2, 1961), cert. den. 368 U. S. 831, is not to the contrary. While this Court denied certiorari, neither the denial nor the appellate decision resolved the constitutional dilemma posed by the instant case. In *United States* v. *40 Cases*, *supra*, the Court of Appeals specifically pointed out that Congressional policy "may not extend to assuring a consumer that *all* representations regarding any device or food made up of components transported in interstate commerce are true." 289 F. 2d at page 346. The seizure was sustained on the finding that the ingredients of the product were oil and the finished product was oil of the very same type, 289 F. 2d at page 346.

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* In *Hipolite Egg Co.* v. *United States*, 220 U. S. 45 (1911) this Court sustained jurisdiction over adulterated eggs which had moved in interstate commerce while the eggs were in their unbroken packages after they had come to rest. This Court, however specifically left open the constitutional question of whether the adulterated article "might be pursued beyond the original package" 220 U. S. at page 57. See also *McDermott* v. *Wisconsin*, 228 U. S. 115, 136 (1913).

In the instant case, however, the record is clear that the product under seizure was a newly manufactured product whose ingredients had been fully consumed in the manufacturing process. It is undisputed in this record that the ingredients were no longer distinguishable as such in the final product.

In *Ewing-Von Allmen Dairy Co. Inc., et al.* v. *C. and C. Ice Cream Co., Inc.*, 109 F. 2d 898 (C. A. 6, 1940), a similar question was posed. There, the Sixth Circuit Court of Appeals, contrary to its decision in the instant case, found that the ingredients of ice cream cones were deemed distinct and different from the ice cream cone itself, so that once the ingredients were consumed in the manufacture of the ice cream cones, interstate commerce had ceased and further regulation was beyond the power of Congress.

See, also:

Brosious v. *Pepsi-Cola Co.*, 155 F. 2d 99 (C. A. 3, 1946);

Jewel Tea Co. v. *Williams*, 118 F. 2d 202 (C. A. 10, 1941);

Lawson v. *Woodmere, Inc.*, 120 F. Supp. 267 (1954);

United States v. *An article at device . . . Consertron*, 180 F. Supp. 52 (1959).

To the same effect, when bauxite is manufactured into aluminum, the ingredient is no longer distinguishable as such in the final product and when a loaf of bread is manufactured from flour, butter, eggs and yeast, the ingredients are no longer distinguishable as such in the loaf of bread. The decision of the Court of Appeals, however, would permit Federal regulation over the loaf of bread in

the local retail bakery shop merely because the eggs came from outside of the state. In matter of fact, applying the decision in the instant case to such facts would permit Federal jurisdiction merely because the local retail bakery shop had a sign in its window referring to the fine ingredients of the bread.

This Court is not being asked to judicially narrow Congressional authority "by envisioning extreme possible applications of its different misbranding provisions" as was argued to this Court in *United States* v. *Sullivan, supra*, at page 694. The decision of the Court of Appeals herein constitutes an actual example of an application of the statute to a factual situation so extreme that to uphold the constitutional limitations is in effect to rule that there are no constitutional limitations.

3. The issue of statutory construction involved herein is a recurring and important one involving 21 U. S. C. 334(a). Section 334(a) provides, in part, that:

> "Any article of food, drug, device or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or *while held for sale (whether or not the first sale) after shipment in interstate commerce*, * * * shall be liable to be proceeded against while in interstate commerce or at any time thereafter, on a libel of information * * * ".

The Court of Appeals' ruling involves the application of the language "while held for sale (whether or not the first sale) after shipment in interstate commerce" to a product which itself had never moved in interstate commerce but which was manufactured from ingredients from out of the state but fully consumed in the manufacturing process. In applying this language to the facts

of the instant case, it would appear that the Court of Appeals overlooked this Court's construction of the phrase "held for sale" in *Hipolite Egg Co. v. United States, supra*, and the legislative history underlying its enactment.

In the *Hipolite* case, *supra*, this Court stated that "all articles, compound or single, not intended for consumption by the producer, are designed for sale * * *", 220 U. S. at page 54. The instant case appears to fall squarely within this definition, for here, the interstate ingredients were intended for consumption by the producer *and were in fact consumed by him* in the manufacturing process. As such, these ingredients could no longer be deemed to be "held for sale" when the newly manufactured product found its way to a retailer. In effect, the Court of Appeals has ruled that every product can be deemed to be "held for sale" after shipment in interstate commerce within the meaning of Section 334(a) where the ingredients have moved in interstate commerce, even though the ingredients themselves have been fully consumed in the manufacture of the new product.

The construction of the "held for sale" clause adopted by the Court below is contrary to the Congressional purpose and legislative history underlying its enactment. The history of the "held for sale" clause in Section 334(a) is as follows:

Section 10 of the Pure Food and Drug Act of 1906 conferred condemnation jurisdiction over adulterated or misbranded products being transported from one state to another "for sale or, having been transported, remains unloaded, unsold or in original unbroken packages." Its object was to condemn articles while being transported or when they have reached their destination, provided they

remain unloaded or unsold or in original unbroken packages. *Hipolite Egg Co. v. United States*, 220 U. S. at page 57.

This doctrine came to be known as the "original package" doctrine. While *prima facie* at least, the language of the 1906 Act appeared to authorize seizures only where the goods had been adulterated before or while in interstate commerce, the courts took the position that goods which were in an adulterated condition at the time of seizure were subject to libel regardless of whether they were adulterated when transported, so long as the goods had, in fact, been transported in interstate commerce and as long as they remained in the original packages.

> *United States v. 300 Cans of Frozen Eggs*, 189 Fed. 351, 353 (C. A. 2, 1911) See also: Hearing Before a Subcommittee of the Committee on Interstate and Foreign Commerce, House of Representatives on H.R. 3128 and H.R. 3147, 80th Cong., First Sess. 2, 1947.

In 1938, Section 10 was rewritten so as to delete the words "unloaded, unsold or in original packages" and to substitute the phrase "when introduced into and while in interstate commerce, or at any time thereafter." It is clear, however, that the change in language did not alter the substantive meaning of the prior section.

> Senate Report No. 493, 73rd Cong., Second Sess., page 19; Senate Report No. 361, 74th Cong., First Sess., page 29; House Report No. 2139, 75th Cong., Third Sess., page 4; Hearing on H. R. 3128 and H. R. 3147, 80th Cong., First Sess., page 3, 1947.

In 1946, however, the Court of Appeals in *United States v. Phelps Dodge Mercantile Co.*, 157 F. 2d 453 (1946),

held that the language of the 1938 Act did not permit the seizure of articles contaminated while held for sale after interstate commerce even though the exercise of such authority had been thought to exist even under the 1906 Act. Thereafter, to correct the problem created by the *Phelps Dodge* decision, *supra*, Congress enacted the *Miller Amendment*, 62 Stat. 582 (1948) to restore the federal authority to make seizures under the same circumstances as had been thought to exist previously under the 1906 and 1938 Acts.

> Senate Report No. 1221, U. S. Code, Congressional and Administrative News, 80th Cong., 2d Sess., pages 2120, 2121.

Indeed, the legislative hearings on the bill show that both the House and Senate Committee had specifically included the "while held for sale" clause in the *Miller Amendment* to restore the authority which had existed for 32 years under the 1906 Act to seize articles that had become adulterated or misbranded while unloaded, unsold, or in original unbroken packages after having moved in interstate commerce.

> Hearing before Subcommittee on Interstate and Foreign Commerce, House of Representatives on H. R. 3128 and 3147, 80th Cong., First Sess., page 23, 1947.

Clearly, therefore, the *Miller Amendment* which enacted the present language of Section 304 of the Act, was intended to make possible the seizure of products which had moved in interstate commerce without proof as to when the adulteration or misbranding had occurred. To effectuate that purpose, the *Miller Amendment* clarified the phrase "when introduced into, while in interstate

commerce or at any time thereafter," by inserting the words "or while held for sale (whether or not the first sale) after shipment in interstate commerce."

It is submitted, however, that the enactment of the *Miller Amendment* did not change the requirement that for jurisdiction to exist, the articles sought to be condemned must at one time move in interstate commerce. The *Miller Amendment* and the "while held for sale" clause did not authorize the seizure of a product which had never moved in interstate commerce, nor did it evince an intention to authorize the seizure of products made from ingredients which have been fully consumed in the manufacturing process, which themselves have never been contraband.

This Court's decision in *United States* v. *Sullivan*, *supra*, is not to the contrary. The *Sullivan* case, *supra*, involved a product which had itself moved in interstate commerce and which had become misbranded after such movement and "while held for sale." The product in the *Sullivan* case, *supra*, did not, as here, become misbranded after properly labeled interstate ingredients had been fully consumed in the manufacturing process. In the *Sullivan* case, *supra*, this Court upheld jurisdiction only with respect to a product which had moved in interstate commerce and whose label had become mutilated after it had come to rest.

Petitioner submits that the construction by the Court below of the "held for sale" clause is inconsistent with the holding of this Court in the *Hipolite Egg* case, *supra*, and is contrary to the underlying statutory purpose and legislative history of Section 334(a).

Petitioner submits that this issue of statutory construction should be resolved in that the very same question has been raised in a number of cases in the district courts and courts of appeals.

United States v. *An article of device . . . Consertron, supra;*
United States v. *40 cases . . . Pinocchio Brand, supra;*
United States v. *Allbrook Freezing & Cold Storage*, 194 F. 2d 937 (1952).

Petitioner respectfully submits that there are here involved important constitutional and statutory questions which should be resolved and that the settlement thereof is in the public interest.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted,

MILTON A. BASS,
SOLOMON H. FRIEND,
Counsel for Petitioner.

Dated: June 26, 1964.

APPENDIX A

Memorandum and Order Denying Motion for Partial Summary Judgment

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

CIVIL ACTION NO. 20215

UNITED STATES OF AMERICA,

vs.

An article of drug consisting of 39 cases, more or less, each containing 48 60-tablet bottles, and 1 case, containing 24 60-tablet bottles, more or less, labeled in part:

(bottle)

"Mich. Brand Korleen Tablets Contains: Choline Citrate, Inositol, Methionine, Cysteine, Niacinamide, Thiamin (Vitamin B1) with excipients. 60 tablets * * * Lelord Kordel of Michigan, Detroit * * * 6009"

etc.

At a session of said court held in the Federal Building, in the City of Detroit, Michigan, this 14th day of March, 1961.

Present: HONORABLE THEODORE LEVIN
Chief United States District Judge

The claimant has filed this motion for partial summary judgment on the ground that the seized "Michigan Brand

"Korleen Tablets" were not shipped in interstate commerce or held for sale after shipment in interstate commerce and consequently are not subject to the provisions of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. §301 *et seq.*

The Government, in the libel of information, alleged that the Korleen Tablets were misbranded while being held for sale after shipment in interstate commerce. 21 U. S. C. A. §334(a). The Tablets are manufactured in Michigan for distribution only in that state, but the component ingredients are shipped in interstate commerce to the manufacturer. The claimant contends that any misbranding must be with respect to an article which is in itself shipped in interstate commerce or held for sale after shipment in interstate commerce, and not to a product created from ingredients shipped in interstate commerce.

The Government claims that Korleen Tablets are a "drug" within the definition set out in 21 U. S. C. A. §321(g):

> "The term 'drug' means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any device specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories."

Five of the six active ingredients of Korleen Tablets, choline, inositol, methionine, niacinamide, and thiamine, are "drugs," being listed in the official United States Pharmacopoeia or the official National Formulary. The representations in leaflets circulated in connection with the sale of the product also demonstrate that the Tablets are a "drug" within clauses (2) and (3) of the statutory definition. See *United States* v. *16 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336 (D. C. N. J. 1953).

The claimant argues that the active ingredients are in common usage in the industry and lose their identity as individual components when combined to form Korleen Tablets. One of the leaflets forming the basis for the Government's accusation of mis-branding emphasizes the treatment of certain disorders through the utilization of choline. The leaflet then mentions that Korleen Tablets contain ". . . large amounts of Choline combined with Inositol, Methionine, etc."

It is evident that if only choline or the other "drugs" comprising the Tablets were shipped in interstate commerce to Michigan, tableted, and misbranded, the "drugs" would be subject to seizure under the Act. It would be a strained interpretation to say that each "drug" component falls within the jurisdiction of the Act, being shipped in interstate commerce, but, when compounded together to form another "drug," the finished product is not being held for sale after shipment in interstate commerce. The result would be especially incongruous in this case in view of the emphasis placed in advertisements upon the alleged therapeutic value of the active components of Korleen Tablets. The logical conclusion of the claimant's argument is that a separate manufacturing and distributing operation could be estab-

lished in each state to manufacture that state's brand of Korleen Tablets from ingredients shipped in interstate commerce, and yet none of the tablets would have been "* * * held for sale * * * after shipment in interstate commerce." The Supreme Court has warned against creating "loopholes," at the expense of public protection, through restrictive or technical constructions of the Act. See *Kordel* v. *United States*, 335 U. S. 345, 349 (1948); *United States* v. *Urbuteit*, 335 U. S. 355, 357-8 (1948).

The claimant states this case is indistinguishable from *United States* v. *An Article or Device Consisting of 31 Units*, 180 F. Supp. 52 (E. D. Mich. 1959), an opinion of this Court, and *United States* v. *40 Cases, More or Less*, 188 F. Supp. 290 (N. D. N. Y. 1960). In both cases, the Courts held that an article or device is not subject to the jurisdiction of the Act where the only components shipped in interstate commerce were either a minor ingredient of the final product or several commonly used components which lost their identity within the newly manufactured device. In contrast, in the case at bar, the "drugs" comprising the Korleen Tablets are the very heart of the manufactured and tableted "drug" and were proclaimed as such to the public.

The claimant's motion for a partial summary judgment is denied.

THEODORE LEVIN
Chief United States District Judge

Opinion of the United States Court of Appeals for the Sixth Circuit

No. 15287

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

Appeal from the United States District Court for the Eastern District of Michigan, Southern Division

UNITED STATES OF AMERICA,
Libelant-Appellee,

v.

DETROIT VITAL FOODS, INC.,
Claimant-Appellant.

Decided March 31, 1964

Before: MILLER and CECIL, Circuit Judges, and McALLISTER, Senior Circuit Judge.

McALLISTER, Senior Circuit Judge. The government filed a Libel of Information under the Federal Food, Drug and Cosmetic Act (21 U. S. C. A. Section 301 et seq.), alleging that articles in the possession of Detroit Vital Foods, Inc., and known as "Michigan Brand Korleen Tablets" and "Lelord Kordel's 'Frutex' Fruit Salad and Vital Foods * * * 'Frutex' Fruit Salad" were drugs which were misbranded while held for sale after shipment in interstate commerce.

The Libel alleged that the drugs were misbranded in that the labeling contained false and misleading repre-

sentations that the drugs were an adequate and effective treatment for hardening of the arteries, defatting of the liver, coronary attacks, cirrhosis of the liver, varicose veins, sore throat, arthritis, drainage of the eyes, inflammation of the eyes, swelling of joints, degeneration of the liver, gall bladder distress, high blood pressure, premature aging, brain fag, prevention of air and foodborne poisonings, impaired circulation, bleeding gums, soft gums, receding gums, nose bleeding, bloodshot eyes, capillary fragility, fever, aches and pains of fever, common colds, fatigue, alcoholism, loose teeth, sneezing, pyorrhea, fibroid tumors of the uterus,, brown pigmentation spots on the skin, prostate gland trouble, prevention of old age, holding of cells together, neutralizing the effect of cigarette smoke, preventing blood vessels and capillaries from bursting, preventing cells within the retina from breaking down, improving the condition of the blood vessels, and neutralizing the toxins in aspirin tablets.

The labeling which the government complained of, as misbranding, was stated to have been contained in leaflets accompanying the drugs, and lectures offered by Lelord Kordel, President of the Detroit Vital Foods, Inc., in promoting sales of the articles; and the government charged that the labeling failed to bear adequate directions for use for the purposes for which the drugs were intended, and that it was misleading and false, all in violation of the Federal Food, Drug and Cosmetic Act, above mentioned. The drugs and literature, used in connection with their proposed sale, were seized by the United States Marshal, pursuant to monition issued out of the District Court.

Mislabeling and misbranding are perils to the public to which many of the provisions of the Federal Food, Drug and Cosmetic Act are directed. The dangers of misrepre-

sentations in literature accompanying drug products, such as in this case, have nowhere been pointed out so well as in the case of *United States* v. *Kordel*, 164 F.2d 913, 916, 917 (C. A. 7), where the president of the claimant company, in the instant case, was defendant. The court, in upholding his conviction, said:

> "With respect to the misrepresentations contained in the accompanying literature we think there can be no serious question. The two booklets, 'Nutrition Guide,' and 'What you can do about relieving the agonies of Arthritis,' were written by appellant who, in the latter, is described as 'America's leading vitamin and diet expert'. 'Health Today, Spring 1945,' is edited by the same 'famous nutrition and vitamin authority.' While all purport to be scientific publications of general interest apart from the articles produced and marketed by appellant, written by an expert in the field, in fact, all are replete with references to the Kordel products and their uses to prevent, ameliorate or cure a vast and diverse variety of ailments, and each conveniently closes with a price list of the various Kordel products recommended for use therein. All are concerned primarily with promoting the sale of the various products by explaining the need for each, along with extravagant claims as to the usefulness of each. A study of the three pamphlets reveals that the products therein described are recommended for relieving stomach agonies, general weakness, anemia, premature old age, high blood pressure, liver troubles, failing eyesight, sore feet; maintaining blood energy, muscular activity, sound teeth and gums, healthy skin, hair and eyes, normal functioning of the pituitary and thyroid glands, stomach, intestines, colon, liver

and kidneys; and preventing arthritis and stiff joints, excess weight, catarrh, nervous breakdown, sterility, and paralysis.

"Thus the scheme devised by appellant for the distribution of his products and related literature contemplates an elaborate system of self-diagnosis and medication. The danger inherent in this system lies not in any positive unwholesomeness of the articles themselves. As to them as such there is no charge and it may be that they are quite harmless in and of themselves. The danger however, lies in the fact that ignorant and gullible persons are likely to rely upon them instead of seeking professional advice for conditions they are represented to relieve or prevent. The Government introduced the evidence of many very eminent men in the medical profession to prove the dangerously misleading character of the literature in that the drugs were useless to combat the conditions they were represented to relieve, while delay in correct diagnosis and treatment for those conditions might render treatment useless. As one of them stated, the literature encouraged people to experiment with themselves and that meant they were gambling with their health and life. He branded as scientifically ridiculous and nonsensical various of the claims and, when asked whether he would say that the products in themselves were harmful, replied: 'They are definitely harmful in that they encourage a patient with a serious disease to experiment with himself when he should seek medical advice and precise diagnosis and therapy.'

"All were agreed that while the claims were absurd and fantastic, they were dangerous in that they tended to lull people into a false sense of se-

curity in reliance on the drugs when they might need professional diagnosis and treatment for conditions which might respond to treatment if correctly diagnosed early enough, but which might become much more serious if not taken care of early. Since the literature which we have already held accompanied the products embodies such misleading representations, it constitutes misbranding within the meaning of the Act."

After numerous pleadings, motions, interrogatories, amendments, objections, and hearings, a consent decree of condemnation was ordered by the District Court. This consent decree is unusual in that it states that the claimant, Detroit Vital Foods, Inc., in consenting to the entry of the decree, specifically reserves "its right to appeal the ruling of the Court herein on the jurisdictional question pertaining to the Korleen tablets." The consent decree adjudged that the drug "Korleen" was misbranded while held for sale after shipment in interstate commerce, in violation of Title 21 U. S. C. A., Sections 352(a) and 352(f)(1); and that the article of food and drug, "Vital Foods Special Brand 'Frutex' Fruit Salad" was misbranded when introduced thereto, while in, and while held for sale after shipment in interstate commerce, in violation of Title 21, U. S. C. A. Section 343(a), 343(i)(2), 352(a), and 352(f)(1). The articles were, therefore, condemned, pursuant to Title 21 U. S. C. A., Section 334(a). The consent decree further ordered that the United States Marshal destroy all literature seized with the drug products, except two books, "Eat and Grow Younger," and "How to Make People Like You."

The Court, however, decreed that the Marshal should release the seized drugs to the custody of the claimant for the purpose of bringing the articles into compliance with

the provisions of the Federal Food, Drug and Cosmetic Act, upon claimant's giving a bond conditioned that it would so do. It was further decreed that, after filing the bond, the claimant should give written notice to the Food and Drug Administration of the Department of Health, Education and Welfare that it was prepared to bring said articles into compliance with the Act, under the supervision of a duly authorized representative of the Secretary of such Department, and that the claimant should, at all times and until the articles had been released by a duly authorized representative of the Secretary, retain the articles for examination or inspection by such representative and should maintain records or other proof necessary to identify such articles to his satisfaction. The court further ordered that the claimant should, under no circumstances, sell or dispose of the articles until the representative of the Secretary had made what examinations were deemed necessary, and, in writing, released the articles for shipment, sale, or other disposition.

Upon the entry of the decree, the claimant, Detroit Vital Foods, Inc., filed its appeal to this Court "from so much of the final decree and judgment entered * * * as condemns * * * 'Michigan Brand Korcom' Tablets," and which adjudged that the article was misbranded while held for sale after shipment in interstate commerce within the meaning of the Federal Food, Drug and Cosmetic Act.

As heretofore mentioned, the consent decree provided that the right was specifically reserved to claimant "to appeal the ruling of the Court herein on the jurisdictional question pertaining to the 'Korcom' tablets."

This "jurisdictional question" is found in the proceedings in the case wherein claimant made a motion for a partial summary judgment, which was denied by the Dis-

trict Court in an opinion and formal order. The claimant had contended that the government had no jurisdiction to seize the drugs for misbranding while being held for sale after shipment in interstate commerce, because the drug seized was a new compound manufactured in the State of Michigan and had not theretofore been shipped in interstate commerce. The fact that the drug in question had been manufactured by mixing several other drugs shipped in interstate commerce did not result, according to the claimant, in the new mixture's being a drug held for sale after shipment in interstate commerce.

The question for determination is whether the ingredients of the Korleen tablets, which was the drug seized, lose their identity as individual components when combined to form such tablets. As Judge Levin found, in the District Court: "Five of the six active ingredients of Korleen Tablets, choline, inositol, methionine, niacinamide, and thiamine, are 'drugs,' being listed in the official United States Pharmacopoeia or the official National Formulary. The representations in leaflets circulated in connection with the sale of the product also demonstrate that the Tablets are a 'drug' within * * * the statutory definition."

The claimant contends that the active ingredients lose their identity as individual components, when combined to form Korleen tablets. One of the leaflets circulated in connection with the sale of the seized product emphasized that choline was a most interesting and valuable vitamin, and went on to tell what choline tends to do in helping many physical afflictions such as fatty liver and fatted arteries, and suggested that choline is a remedy for such arteries, and for hardened cerebral arteries. The leaflet further stated that Korleen "is the name of a wonderful new product containing large amounts of Cho

line—combined with Inositol, Methionine, etc." It further declares that "it is wise to add really high amounts of Choline—Inositol—Methionine to supplement our daily diet." The value of each of the ingredients making up Korleen tablets is emphasized. These ingredients are, so to speak, put in a package together. In their combination, they do not form something new and different. As far as can be perceived from the representations made to the public, the ingredients are mixed and pressed into tablets which offer several different drugs in one dose. The case is similar to *United States* v. *40 Cases* * * * *Pinocchio Brand*, 289 F. 2d 343, 346 (C. A. 2), where several different vegetable oils were combined. It was argued that such processing created a new product which was different from the ingredient oils that had been shipped in interstate commerce. The court overruled this contention, saying:

> "We would be undermining the remedial legislative purpose of consumer protection were we to deny the power to seize misbranded articles on the ground that such foods as corn oil, peanut oil, soya bean oil and olive oil when mixed constitute a 'different product' from a blend of less than all or from a pure measure of any one of them."

Finally, claimant contends that the seizure provisions of the Federal Food, Drug and Cosmetic Act, as interpreted by the District Court, are unconstitutional. The argument reverts to the claim that "Korleen Tablets" constitute a new product different in kind and nature from the ingredient drugs and that, consequently, since "Korleen Tablets" do not move in interstate commerce, they are not subject to seizure under the Act. It is urged that while the ingredient drugs did move in interstate commerce, they were not claimed to have been misbranded. These

ingredient drugs, however, when combined in Detroit, were misbranded. The statutory purpose of the Act was "to safeguard the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer * * *. The words * * * 'while such article is held for sale after shipment in interstate commerce' apparently were designed to fill this gap and to extend the Act's coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer." *United States* v. *Sullivan*, 332 U. S. 689, 696, 697. As Mr. Justice Black said, in speaking for the court in the above-mentioned case, the "purpose [of the Act] would be frustrated when the pills the consumer buys are not labeled as required, whether the label has been torn from the original container or the pills have been transferred from it to a non-labeled one." *Supra*, 695. So, the removal of drug from a container, labeled in accordance with requirements of the Act, to one not so labeled, is the doing of an act which results in their being "misbranded" within the meaning of Section 301 (k). As Judge Levin, in the District Court, remarked: "The Supreme Court has warned against creating 'loopholes,' at the expense of public protection, through restrictive or technical constructions of the Act. See *Kordel* v. *United States*, 335 U. S. 345, 349 (1948); *United States* v. *Urbuteit*, 335 U. S. 355, 357-8 (1948)."

It is our view that by misbranding "Korleen Tablets," made from ingredient drugs that had been properly labeled in the course of interstate commerce, the misbranding came within the prohibitory provisions of the Federal Food, Drug and Cosmetic Act.

In accordance with the foregoing, the judgment of the District Court is affirmed.

Judgment of the United States Court of Appeals for the Sixth Circuit

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

No. 15,287

Filed
March 31, 1964

Before: MILLER and CECIL, Circuit Judges, and MCALLISTER, Senior Circuit Judge.

APPEAL from the United States District Court for the Eastern District of Michigan.

THIS CAUSE came on to be heard on the transcript of the record from the United States District Court for the Eastern District of Michigan, and was argued by counsel.

ON CONSIDERATION WHEREOF, It is now here ordered and adjudged by this Court that the judgment of the said District Court in this cause be and the same is hereby affirmed.

No costs awarded. Rule 23(4)

Approved for entry:

/s/ THOMAS F. MCALLISTER,
Senior Circuit Judge

APPENDIX B

Statutes

The Federal Food, Drug and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040 (21 U. S. C. 301, *et seq.*), provides in pertinent part:

Sec. 304(a):

> "Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * * [21 U. S. C. 334(a)]"

Article I, Section 8, Clause 3 of the Constitution of the United States.

> "**Art. I. Sec. 8, Cl. 3. Power of Congress to regulate commerce.**—To regulate commerce with foreign nations, and among the several states, and with the Indian tribes."

Tenth Amendment to the Constitution of the United States.

AMENDMENT 10

> "**Rights reserved to states or people.** The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."